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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,897	11/28/2001	Pierre D. Mourad	12500.2001U	1505

20601 7590 08/25/2004
SPECKMAN LAW GROUP PLLC
1501 WESTERN AVE
SEATTLE, WA 98101

EXAMINER

IMAM, ALI M

ART UNIT PAPER NUMBER

3737

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,897

Applicant(s)

MOURAD ET AL.

Examiner

Ali Imam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-21, 35-44, 46-58, 60-69 and 74-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10, 13-21, 36-44, 50-58, 60, 61, 65-68, 75-85 and 95 is/are allowed.
- 6) ☒ Claim(s) 35, 46-49, 62-64, 69, 74 and 86-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/10/4.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In regard to the amendment filed 05/10/2004, all necessary changes to the claims have been entered.

Response to Arguments

2. Applicant's arguments, see pages 15-16, filed 05/10/2004, with respect to claims 1-10, 13-21, 36-44, 50-58, 60, 61, 65-68, 75-85, and 95 have been fully considered and are persuasive. The rejection of claims 1-10, 13-21, 36-44, 50-58, 60, 61, 65-68, 75-85, and 95 has been withdrawn.

3. Applicant's arguments filed 05/10/2004 with respect to claims 35, 46-49, 62-64, 69, 74, and 86-94 have been fully considered but they are not persuasive. Applicant's core argument is that Michaeli does not teach the steps of inducing oscillation of the CNS target tissue and measuring at least one of the frequency and amplitude of an acoustic signal. The examiner respectfully disagrees. Michaeli's method is to assess physiological property of a CNS tissue by inducing ultrasound energy at the target tissue (col. 12, lines 41-45). Without providing any oscillation at the target site no acoustic signal can be obtained for physiological assessment. Furthermore, Michaeli's acoustic data containing physiological assessment data inherently includes data relating to a physiological condition or biological response including pain. Focused ultrasound probing technique is well known in the art of ultrasound diagnostic and therapeutic technique, see e.g., Klopotek (US 6,113,559).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 35, 46-49, 62-64, 69, 74, and 86-94 are rejected under 35 U.S.C. 102(e) as being anticipated by Michaeli (US 6,328,694 B1 of record).

6. Michaeli teaches in cols. 12-32, a method and system for assessing physiological property of target tissue (col. 12, line 32-35) including CNS tissue (col. 12, line 41-54) by the steps and structures for collecting acoustic data by using an ultrasound probe (101) that inherently includes ultrasound transducers; relating the acoustic data with a physiological property of the target tissue; and displaying the information on a display. Michaeli further teaches the steps and structures for quantitative measurements of tissue elasticity (col. 12, lines 40-41). Furthermore, acoustic data inherently includes frequency and/or amplitude of an emitted acoustic signal. Since Michaeli teaches the steps of inducing ultrasound energy at the target site, it is anticipated that such energy would oscillate the target tissue to generate physiological parameter. Furthermore, Michaeli's acoustic data containing physiological assessment data inherently includes data relating to a physiological condition or biological response including pain. Focused ultrasound probing technique is well known in the art of ultrasound diagnostic or therapeutic technique, see e.g., Klopotek (US 6,113,559).

Allowable Subject Matter

7. Claims 1-10, 13-21, 36-44, 50-58, 60, 61, 65-68, 75-85, and 95 are allowed.
8. The following is an examiner's statement of reasons for allowance: the primary reason for allowance is the inclusion of the steps of determining the induced tissue displacement and relating the induced tissue displacement with a physiological property of the CNS target tissue in all of the allowed independent claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Imam whose telephone number is 703-305-0028. The examiner can normally be reached on Mon. - Th., 8:00- 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ali Imam
Primary Examiner
Art Unit 3737

AMI
8/22/2004